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## TRANSMITTAL FORM

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Total Number of Pages in This Submission

6

Application Number

10/713,642

Filing Date

11/13/2003

First Named Inventor

David S. F. Young

Art Unit

1641

Examiner Name

Attorney Docket Number

2056.026

### ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
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<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
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### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	McHale & Slavin, P.A.		
Signature			
Printed name	Ferris H. Lander		
Date	6/27/2005	Reg. No.	43,377

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICANT : David S. F. Young et al  
INVENTION : CANCEROUS DISEASE MODIFYING ANTIBODIES  
SERIAL NUMBER : 10/713,642  
FILING DATE : November 13, 2003  
EXAMINER :  
GROUP ART UNIT : 1641  
ATTORNEY DOCKET NO. : 2056.026

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Sir:

Pursuant to the Duty to Disclose under 37 CFR §1.56, the references cited on the accompanying forms PTO/SB/08A and PTO/SB/08B are hereby brought to the attention of the Examiner for independent evaluation. A copy of each reference is enclosed. The references were cited in the specification and their relevancy is set forth therein.

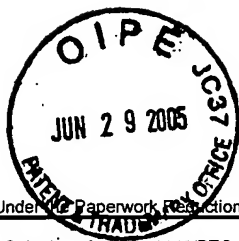
Applicants submit that the present invention is patentable over these references.

Date 6/27/2005

Respectfully submitted,

By Ferris H. Lander

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PTO/SB/08A (08-03)

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/713,642
Filing Date	11/13/2003
First Named Inventor	David S. F. Young
Art Unit	1641
Examiner Name	
Attorney Docket Number	2056.026

Sheet 1 of 4

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 5,750,102	05/12/1998	L. Eisenbach et al	
		US- 4,861,581	08/29/1989	A. Epstein et al	
		US- 5,171,665	12/15/1992	I. Hellstrom et al	
		US- 5,484,596	01/16/1996	M. Hanna, Jr., et al	
		US- 5,693,763	12/02/1997	J. Codington et al	
		US- 5,783,186	07/21/1998	T. Arakawa et al	
		US- 5,849,876	12/15/1998	P. Linsley et al	
		US- 5,869,268	02/09/1999	T. Kudo et al	
		US- 5,869,045	02/09/1999	I. Hellstrom et al	
		US- 5,780,033	07/14/1998	V. Torchilin et al	
		US- 6,180,357	01/30/2001	D. Young et al	
		US- 4,172,124	10/23/1979	H. Koprowski et al	
		US- 6,657,048	12/02/2003	D. Young et al	
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
		WO95/20401	08/03/1995	Trustees of Boston University		

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				Application Number	10/713,642
				Filing Date	11/13/2003
				First Named Inventor	David S. F. Young
				Art Unit	1641
				Examiner Name	
Sheet	2	of	4	Attorney Docket Number	2056.026

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		D. HARRIS et al, "Serotherapy of cancer", Seminars in Oncology, 16(3):180-198 (June, 1989)	
		H. DVORAK et al, "Structure of solid tumors and their vasculature: implications for therapy with monoclonal antibodies", Cancer Cells, 3(3):77-85 (March, 1991)	
		S. ENGELHOLM et al, "Disaggregation of human solid tumours by combined mechanical and enzymatic methods", Br. J. Cancer, 51:93-98 (1985)	
		A. COSTA et al, "Implications of disaggregation procedures on biological representation of human solid tumours", Cell Tissue Kinet., 20:171-180 (1987)	
		S. DAIRKEE et al, "Partial enzymatic degradation of stroma allows enrichment and expansion of primary breast tumor cells", Cancer Research, 57:1590-1596 (April, 1997)	
		B. FRANZEN et al, "Nonenzymatic extraction of cells from clinical tumor material for analysis of gene expression by two-dimensional polyacrylamide gel electrophoresis", Electrophoresis, 14:1045-1053 (1993)	
		E. HOLZ et al, "Antibody-based immunotherapeutic strategies in colorectal cancer", Recent Results in Cancer Research, 142:381-400 (1996)	
		R. DILLMAN, "Antibodies as cytotoxic therapy", J. Clin. Oncol., 12(7):1497-1515 (July, 1994)	
		R. DILLMAN, "Monoclonal antibodies for treating cancer", Annals of Internal Medicine, 111:592-603 (1989)	
		M. DISIS et al, "HER-2/neu protein: a target for antigen-specific immunotherapy of human cancer", Advances in Cancer Research, 71:343-371 (1997)	

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		Application Number	10/713,642		
		Filing Date	11/13/2003		
		First Named Inventor	David S. F. Young		
		Art Unit	1641		
Examiner Name					
Sheet	3	of	4	Attorney Docket Number	2056.026

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		A. BEGG et al, "Rapid fluorescence-based assay for radiosensitivity and chemosensitivity testing in mammalian cells in vitro", Cancer Research, 49:565-569 (February, 1989)	
		J. CRUSE et al, Illustrated Dictionary of Immunology, CRC Press, p. 280 (1995)	
		A. KNUTH et al, "ADCC reactivity of human melanoma cells with mouse monoclonal antibodies", Proc. Am. Assoc. Cancer Res., 25:1005 (March, 1984) Abstract only	
		J. HOROSZEWICZ et al, "Monoclonal antibodies to a new antigenic marker in epithelial prostatic cells and serum of prostatic cancer patients", Anticancer Research, 7:927-936 (1987)	
		D. HERLYN et al, "Monoclonal anticolon carcinoma antibodies in complement-dependent cytotoxicity", Int. J. Cancer, 27:769-774 (1981)	
		V. KRAVTSOV et al, "Automated monitoring of apoptosis in suspension cell cultures", Laboratory Investigation, 74(2):557-570 (1996)	
		L. HARTWELL et al, "Integrating genetic approaches into the discovery of anticancer drugs", Science, 278:1064-1068 (November, 1997)	
		B. CURTI, "Physical barriers to drug delivery in tumors", Critical Reviews in Oncology/Hematology, 14:29-39 (1993)	
		R. JAIN, "Barriers to drug delivery in solid tumors", Scientific American, 271(1):58-65 (July, 1994)	
		T. GURA, "Systems for identifying new drugs are often faulty", Science, 278:1041-1042 (November, 1997)	

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**INFORMATION DISCLOSURE  
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)	<b>Application Number</b>		10/713,642		
	<b>Filing Date</b>		11/13/2003		
	<b>First Named Inventor</b>		David S. F. Young		
	<b>Art Unit</b>		1641		
	<b>Examiner Name</b>				
<b>Sheet</b>	4	<b>of</b>	4	<b>Attorney Docket Number</b>	2056.026

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		G. DERMER, "Another anniversary for the war on cancer", Bio/Technology, 12:320 (March, 1994)	
		R. FRESHNEY, "Culture of animal cells", a Manual of Basic Technique, Alan R. Liss, Inc., New York, p. 3 (1983)	
		T. HSU, "Karyology of cells in culture - a preparation and analysis of karyotypes and idiograms", in Tissue Culture Methods and Applications, eds. Kruse and Patterson, Academic Press, New York, pp. 764-767 (1973)	
		M. EMBLETON, "Monoclonal antibodies to osteogenic sarcoma antigens", Immunol. Ser., 23:181-207 (1984)	
		H. DREXLER, "Recent results on the biology of Hodgkin and Reed-Sternberg cells", Leukemia and Lymphoma, 9:1-25 (1993)	
		C. BADGER et al, "Prospects for monoclonal antibody therapy of leukemia and lymphoma", Cancer, 58:584-589 (1986)	
		E. BOVEN et al, "Monoclonal antibodies in cancer treatment: where do we stand after 10 years?", Radiotherapy and Oncology, 5:109-117 (1986)	
		A. EPSTEIN et al, "Two new monoclonal antibodies, Lym-1 and Lym-2, reactive with human B-lymphocytes and derived tumors, with immunodiagnostic and immunotherapeutic potential", Cancer Research, 47:830-840 (1987)	
		K. FOON, "Biological therapy of cancer", Breast Cancer Research & Treatment, 7:5-14 (1986)	

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